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EXAMINER	
RAE, CHARLESWORTH E	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/761,358	KOIKE ET AL.	
	Examiner	Art Unit	
	Charleswort Rae	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, filed 02/09/07, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of actions being applied to the instant application.

Applicant's Clear and Conspicuous Statement of Common Ownership of the instant invention and U.S. Patent 6,139,897 (Goto et al.), by Kao Corporation, at time the instant invention was made is acknowledged and made of record.

Applicant's statement memoralizing the Interview of January 24, 2007, is acknowledged and made of record.

Status of the Claims

Claims 6-13 are currently pending in this application and are the subject of the Office action.

Claims 1-5 and 14-22 are canceled.

Applicant's response to rejections

Claim rejection under 112, second paragraph, is withdrawn in view of the amendment.

Claim rejection under 103(a) is withdrawn in view of the amendment and applicant's arguments as set forth below (see Applicant's response filed 2/9/07, page 4, last paragraph to page 5, first paragraph):

Diglyceride compositions have gained interest based on a disclosed obesity-preventing effect. In addition, ω-3 type unsaturated fatty acids having at least 20 carbon atoms such as docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA), principle components of fish oil triglycerides, have been reported to have beneficial health properties. ω-3 Type unsaturated fatty acid have been reported to have very poor oxidation stability (page 2, lines 17-19 of the specification) while diglycerides of ω-3 type unsaturated fatty acids have exhibited very high viscosities (page 2, line 27 through page 3, line 5 of the specification). Accordingly, diglyceride containing compositions of ω-3 unsaturated fatty acids having good stability and viscosity are sought.

The claimed invention addresses this problem by providing a food product comprising an oil composition and food wherein the diglycide component has 15-89.5 wt. % of ω-3 unsaturated acyl group having at least 20 carbon atoms with 10-84.5 wt% of monoenoic acyl groups. Applicants have discovered that such a distribution of ω-3 unsaturated fatty acids and monoenoic acyl groups provide for an oil composition having good stability and viscosity. Such a composition is nowhere disclosed or suggested in the cited and applied prior art of record.

Objections to Minor Informalities under 37 CFR 1.71

The disclosure is objected to because of the following informalities: pages 6, 8, 10, 12, 17, 23, 24, and 28 contain missing/eligible information and/or extraneous markings, which do not comply with 37 CFR 1.71. This objection may be overcome by the filing corrected copies to replace the defective pages. The filed replacement pages must be accompanied by a statement that they contain no new matter.

Appropriate correction is required.

New Rejections

Claim rejections – 35 USC 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 6 is rejected under 102(b) as being anticipated by Howard et al. (US Patent 3,268,337).

Claim 6 is rejected under 102(b) as being anticipated by Howard et al. (US Patent 3,268,337).

Howard et al. teach alpha-phase crystal-tending emulsifiers; namely, 1) **1,3-diglycerides in which one of the acyl groups** comprises a carbon chain of from two to four carbon atoms while the other acyl group comprises a chain of from 16 to 22 carbon atoms, 2) 1,2-diglycerides in which one of the acyl groups comprises a carbon chain of from 12 to 18 carbon atoms and the other acyl group comprises a chain of from **16 to 22 carbon atoms**, and 3) mixtures of 1,3-diglycerides and the isomeric 1,2-diglycerides which are formed during the preparation of the 1,3-diglycerides (column 4, lines 15-27). Howard et al. teach that 1,3-diglycerides can be prepared by various processes, including interesterification of appropriate mixtures of long chain monoglycerides, diglycerides, and/or triglycerides, either with or without glycerol under conditions such that the resulting reactant composition will contain approximately one equivalent of long-chain acyl component, one equivalent of short chain acyl component, and one mole of glycerol; the reaction is effectively catalyzed by basic catalysts such as **sodium methoxide** (column 4, lines 27-47). Howard et al. teach the condensation products of partial fatty acid glycerides or diol monoesters with polycarboxylic acids can be obtained by direct esterification; the preparations are best carried out with reaction **temperatures in the range of from about 75° C. to about 175° C**. with water being removed by evolution under reduced pressure or by azeotropic distillation (column 6, lines 31-64). Howard et al. teach shortenings which can be employed in cake batter include solid or plastic as well as liquid or semi-fluid glyceride shortenings derived from

animal, vegetable or **marine fats and oils**, including synthetically prepared shortenings (column 9, lines 5-9). These glycerides can contain saturated or unsaturated "long-chain" acyl radicals having from about 12 to about 22 carbon atoms such as linoleoyl, linolineoyl, arachidoyl, arachidonoyl, behenoyl, erucoyl, and the like, and are generally obtained from edible oils and fats such as cottonseed oil, soybean oil, coconut oil, **rapeseed oil**, peanut oil, olive oil, whale oil, menhaden oil, sardine oil (column 9, lines 9-29). The shortenings can also contain minor amounts of conventional cake emulsifier such as the higher fatty acid mono- and diglycerides (column 9, lines 29-31). Howard et al. teach that oils predominating in glycerides of unsaturated acids may require partial hydrogenation to maintain flavor (column 2, lines 1-3). Howard et al. do not expressly teach compositions comprising triglycerides, diglycerides, monoglycerides, and free fatty acids.

Instant claim 6 recites the term *"about 0.1 to 59.8% by weight of a triglyceride,"* this term is reasonably construed to **encompass an oil composition comprising zero (0) amount of triglyceride** as someone of skill in the art would reasonably construe "0.1% by weight of triglyceride" as conferring zero functional characteristics to the oil composition. The limitation *"about 0.1 to about 10% by weight of a monoglyceride"* is reasonably construed to **encompass an composition comprising zero (0) amount of a monoglyceride** as someone of skill in the art would reasonably construe "0.1% by weight of a monoglyceride" as conferring zero functional characteristics to the oil composition. The term *"at most about 5% by weight of a free fatty acid"* is reasonably construed to encompass an oil composition comprising zero (0) amount of free fatty

acid. In addition, the process steps form making the diglyceride product taught by Howard et al. are identical to the process steps disclosed in the instant application for making the claimed oil composition (see specification, page 7, line 24 to page 9, line 9; see specifically, Examples 1, 2, 3, and Comparative Example 5).

Thus, the instant claimed oil composition is an inherent product of the well known process taught by Howard et al. for making an acylated diglyceride product (i.e. using rapeseed oil or marine oil as the starting material; sodium methoxide as the rearrangement catalyst; at reaction temperature of from 75 to about 175° C), which would reasonably result in an oil composition comprising 40 to 99.7% of a diglyceride wherein a content of ω-3 unsaturated acyl groups having at least 20 carbon atoms and monoenoic acyl groups in acyl groups constituting the diglyceride are about 15 to 89.5% by weight and about 10 to 84.5% by weight, respectively.

Claim rejections under 103(a)

Alternatively, instant claim 6 is rejected under 103(a) as being unpatentable over Howard et al. (US Patent 3,268,337).

The discussion of Howard et al. in connection with the above 102(b) rejection is incorporated herein.

Based on the teaching of Howard et al. that 1,3-diglycerides can be prepared by various processes, including interesterification of appropriate mixtures of long chain monoglycerides, diglycerides, and/or triglycerides, either with or without glycerol, someone of skill in the art at the time the instant invention was made would have been

motivated to created the instant claimed invention using the process steps of Howard et al.

Thus, it would have been obvious to someone of skill in the art at the time the instant invention was made to create the instant claimed oil composition with a reasonable expectation of success based on the teaching of Howard et al.

Claims 6-13 are rejected under 103(a) as being unpatentable over Volpenhein (US Patent 4,263,216) and Stout et al., in view of Brown et al. (5,288,619), in view of Seiden et al. (US Patent 4,680,184), in view of Ainger et al. (US Patent 4,214,012), in view of Maurrizio Ciani. *Wine vinegar production using base wines made with different yeast species.* J. Sci. food Agric. 1998; 78: 290-294 (already made of record), in view of Young et al. (US Patent 5,085,884).

Instant claim 6 recites the term *"about 0.1 to 59.8% by weight of a triglyceride,"* this term is reasonably construed to **encompass an oil composition comprising zero (0) amount of triglyceride** as someone of skill in the art would reasonably construe *"0.1% by weight of triglyceride"* as conferring zero functional characteristics to the oil composition. Similarly, the limitation *"about 0.1 to about 10% by weight of a monoglyceride"* is reasonably construed to **encompass an composition comprising zero (0) amount of a monoglyceride** as someone of skill in the art would reasonably construe *"0.1% by weight of a monoglyceride"* as conferring zero functional characteristics to the oil composition. In addition, the term *"at most about 5% by weight of a free fatty acid"* does not have a lower a lower limit and is therefore reasonably

construed to encompass an oil composition comprising zero (0) amount of free fatty acid. Thus, the instant claimed oil composition could reasonably be construed as comprising 40 to 99.7% of a diglyceride wherein a content of ω-3 unsaturated acyl groups having at least 20 carbon atoms and monoenoic acyl groups in acyl groups constituting the diglyceride are about 15 to 89.5% by weight and about 10 to 84.5% by weight, respectively.

Volpenhein (US Patent 4,263,216) teaches a process for preparing saturated 1,3-diglycerides comprising the steps of (a) reacting substantially saturated triglycerides (TG) with a reactant selected from glycerol (G) plus glycerolysis catalyst (C) or pre-formed glycerage (PFG), to provide a glycerolysis product which comprises a mixture of monoglycerides (MG), triglycerides (TG), 1,2-diglycerides (1,2-DG) and 1,3-diglycerides (1,3-DG); and (b) storing the glycerolysis product of Step (a) in the presence of a low temperature rearrangement catalyst (LTRC) at a storage temperature below the melting point of the glyceride components of said glycerolysis product for a storage period of **at least about 4 hours** (column 3, lines 53-67). When the glycerolysis step of the foregoing process is carried out properly, the conversion of triglycerides to diglycerides **consistently gives 85% yields of the diglyceride products** within 24 hours (column 5, lines 21-31). Volpenhein teaches that when using natural, unsaturated fats or oils, the glycerolysis catalysts is preferably sodium hydroxide and the rearrangement catalyst is preferably selected from sodium hydroxide, **sodium methoxide** or sodium ethoxide (column 8, lines 35-39); the instant specification discloses sodium methoxide as an alkali metal catalyst. Volpenhein teaches a product recovered from the reference

process and neutralization comprising **greater than 85% diglycerides**; of the diglycerides, greater than 95% were the desired 1,3-diglycerides; the product was of food grade quality suitable for use in the manufacturer of confectioner's butter, or the like (see Example 1; column 8, line 50 to column 33). The Final Product of the overall reaction comprises ca. **5% TG**, ca. **5% MG** and ca. **90% DG**, of which ca. 95%, or greater, is in the desired 1,3-DG form, and **some free fatty acid** (column 4, lines 20-23). Instant claim 6 recites a TG of about 0.1 to 59.8%, a DG of 40 to 99.7%, a MG about 0.1 to 10%, at most about 5% of a free fatty acid, which overlap with the teachings of Volpenhein (column 4, lines 20-23). Volpenhein teaches that the starting material that can be used as the source of the triglycerides is naturally occurring sources such as palm oil and soybean oil that can be converted to **1,3-fatty acid diglycerides** with chain lengths in the range from **about C12 to about C20,** which are the basic raw materials for the manufacture of cocoa butter and the like (column 1, lines 12-18; and column 2, lines 24-45). Volpenhein teaches that the unique melting characteristics of cocoa butter of the invention makes it suitable for use in confectionery products, especially **chocolates** (column 1, line 35); instant claim 12 recites the limitation *"wherein the food product is chocolate."* However, Volpenhien does not teach rapeseed oil or fish oils i.e. omega-3 unsaturated fatty acids.

Stout et al. (US Patent 5,149,851) teach a method to prepare a mixed triglyceride containing an omega-3 or other polyunsaturated fatty acid residue and monoenoic or shorter-chain saturated fatty acid residues (column 7, lines 1-16; see also column 3, lines 6-36)). Stout et al. teach, for example, a concentrate of omega-3 polyunsaturated

fatty acid esters containing 48.8% EPA and 22.9% DHA residues, anhydrous glycerol, and sodium dispersion combined in a round-bottom flask; the flask was evacuated to below 25 mm Hg and flushed with nitrogen, then the mixture was heated at 70 degrees Centrigrade for 22.5 hours (column 4, lines 32-47). Thin-layer chromatography (TLC) on a silica gel plate indicated that the crude product contained 60 % unreacted ester yield of the triglyceride; an overall yield of 75% was realized, based on the amount of glycerol (column 4, lines 52-59). The fatty acid profile of the **triglyceride contained 47.9% EPA and 25.4% DHA fatty acid residues** (column 4, lines 60-63; see also reference claim 8). Such triglycerides are useful because they are a source of polysaturated fatty acids and may be more stable and resistant to oxidation than triglycerides wherein all of the fatty acids are polyunsaturated (column 7. 4-8). Short- and medium-chain-length fatty acid containing triglycerides have different intestinal absorptive properties than triglycerides wherein all of the fatty acid residues are polyunsaturated (column 7, lines 8-12). Thus, triglycerides formed from short- (2 to 7 carbon-containing), medium- (8 to 15 carbon) chain, and/or **monoenoic fatty acids in combination with polyunsaturated fatty acids from fish oils** may be more stable and may be more effectively adsorbed (column 7, lines 12-16). Stout et al. disclose that **fish oils** comprise a complex mixture of fatty acid moieties and that fish and marine mammal oils contain substantial amounts of fatty acids having twenty or twenty-two carbons and four, five or six double bonds (column 1, lines 14-22). Stout et al. also teach that fish and fish oils are the major source of significant quantities of omega-3 eicosanoid precursors, such as EPA and DHA (column 1, lines 53-55).

Brown et al. (5,288,619; **already made of record**) teach enzymatic methods for preparing glycerides and to designed glycerides of specific composition (column 1, lines 14-16). Brown et al. teach that the invention may also be used to introduce specific health-promoting fatty acids e.g. **omega-3 fatty acids such as eicosapentanoic acids,** into triglyceride oils and fats (column 1, lines 26-29). Brown et al. teach that the main components of margarine oils are triacylglycerols (triglycerides), which are trimesters of glycerol and various saturated and unsaturated fatty acids (column 2, lines 53-55). Brown et al teach that egg yolks provide excellent functional emulsification properties for food products such as **mayonnaise** and are necessary or desirable component for many food products such as spoonable and pourable food dressings (column 5, lines 32-36); instant claim 9 recites the limitation *"wherein the food product is mayonnaise."* Brown et al. teach that margarine oils have a broad profile of triglycerides of unsaturated C18 fatty acids in esterified form which produce a wide variety of triglyceride components of the oil (column 7, lines 60-64). Brown et al. teach that sunflower, soybean, safflower, corn, olive and canola (low erucic acid **rapeseed**) oils or blends thereof may be used as starting material for the manufacturer of butter-fat substitute lipid composition (column 30, lines64-68). Brown et al. teach that nutritionally desirable unsaturated fatty acids in appropriate levels and ratios have been identified such that an increase in the omega-3 to omega-6 ratio in the average diet could yield distinct health benefits (column 34, lines 42-46). Brown et al. teach that transesterified di and triglyceride product has an esterifed saturated fatty acid content of less than 3.5 weight percent, and may be used in a wide variety of food products, such as liquid

margarine or cooking oils, **mayonnaise and salad dressings**; instant claim 7 recites the limitation *"wherein the food product is a salad dressing."*

Seiden et al. (US Patent 4,680,184) teach an emulsifier system for cookies comprising a) from about 40% to about 100% (by weight on the basis of monoglyceride content) fatty acid mono-diglycerides, said mono-diglycerides having from about 35% to about 99% fatty acid mono-glycerides, and from about 1% to about 50% fatty acid diglycerides, wherein at least about 65% of said fatty acids are selected from the group consisting of C14-C20 saturated fatty acids and C16-C20 transsaturated fatty acids and mixtures thereof, b) from about 0 to about 60% (by weight) fatty acid esters of polyols having an average of from about 4 to about 14 of the hydroxyl groups, wherein from about 10 to about 66% of the hydroxyl groups are esterified, wherein at least about 65% of said fatty acids are selected from the group consisting of C14-C20 saturated fatty acids and C16-C20 transunsaturated fatty acids and mixtures thereof; and c) from about 0% to about 60% (by weight) fatty acid mono-glyceride esters of polycarboxylic acids and their derivatives, wherein at least about 65% of said fatty acids are C14-C20 saturated fatty acids (abstract). Seiden et al. teach a fatty acid mono-diglyceride component comprises from about 35% to about 99% fatty acid monoglycerides and from about 1% to about 50% fatty acid diglycerides, with small amounts of triglycerides and gree glycerol; at least about 65% of the fatty acids are selected from the group consisting of C14-C20 saturated fatty acids and mixtures thereof (column 3, lines 4-36). Polyglycerols are prepared by the polymerization of glycerine in the presence of either acid or base; the method of making the polyglycerols is not critical to the invention

(column 4, lines 50-56). Seiden et al. teach dough that can be **baked to form a cookie** (column 9, lines 52-55); instant claim 11 recites the limitation *"wherein the food product is a baked food."* Seiden et al. also teach **chocolate chips** (column 12, lines 59-66); instant claim 12 recites the limitation *"wherein the food product is a chocolate."*

Ainger et al. (US Patent 4,214,012) teach fat compositions, including a blend containing 65% coconut oil and 35% dry fractionated palm stearine which was esterified at 115 degrees C using 0.25% sodium methoxide catalyst; the interesterified hardened blend was found to be superior to the standard commercial product with respect to colour, taste and shelf-life and it was evaluated as a **biscuit cream** filling in a blend of no after taste (column 8, line 55 to column 9, line 3; see also column 6, Table 1 and column 9, Table IV); instant claim 10 recites the limitation *"wherein the food product is a cream."*

Maurrizio Ciani. Wine vinegar production using base wines made with different yeast species. J. Sci. food Agric. 1998; 78: 290-294 (**already made of record**) teaches **wine vinegar** is generally recognized to have a higher organoleptic value in comparison with other vinegars (page 290, column 1, first paragraph); instant claim 8 recites the limitation *"wine vinegar."*

Young et al. (US Patent 5,085,884) teach reduced calorie **potato chips** wherein a fat composition is applied to the surface of a potato chip (abstract); the nondigestible fat component comprises a nondigestibler oil and preferably low levels of certain solid polyol fatty acid polyesters having ester groups comprising combinations of unsaturated

(C12 or higher) and/or short chain (C2-C12) saturated fatty acid radicals and long chain (C20 or higher) saturated fatty acid radicals (abstract).

Based on the teaching of Brown et al. of the incorporation of the specific health-promoting fatty acids e.g. **omega-3 fatty acids such as eicosapentanoic acids,** into triglyceride oils and fats (column 1, lines 26-29), someone of skill in the art at the time the instant invention was made would have been motivated to combine the teachings of Volpenhein (US Patent 4,263,216) and Stout et al., in view of Brown et al. (5,288,619), in view of Seiden et al. (US Patent 4,680,184), in view of Ainger et al. (US Patent 4,214,012), in view of Maurrizio Ciani, in view of Young et al. (US Patent 5,085,884), to create the instant inventive concept.

Thus, someone of skill in the art at the time the instant invention was made would have deemed it obvious to created the instant claimed invention with a reasonable expectation of success in view of Volpenhein and Stout, in view of Brown et al., in view of Martin et al., in view of Ainger et al., in view of Ciani, in view of Young et al.

Claims 6-13 are rejected under 103(a) as being unpatentable over Wallach, in view of Brown et al. (5,288,619), in view of Seiden et al. (US Patent 4,680,184), in view of Ainger et al. (US Patent 4,214,012), in view of Maurrizio Ciani. *Wine vinegar production using base wines made with different yeast species.* J. Sci. food Agric. 1998; 78: 290-294 (already made of record), in view of Young et al. (US Patent 5,085,884).

Wallach (US Patent 4,917,951) teach lipid vesicles made of long chain surfactants having at least one lipohilic acyl or alkyl group attached to a hydrophilic

head group (column 2, lines 2-15; column 4, lines 3-36). In one embodiment, the surfactant may be selected from a group consisting of **polyoxyethylene (s) eicosamonoenoyl (C20 single double bond i.e. a monoenoic radical) or polyoxyethylene (t) eicosadienoyl (C20 two double bonds i.e. omega-3 radical) ethers** where s and t ranges from 2-10 (column 4, lines 37-41). Wallach teaches that substantially all the lipid was in the form of lipid vesicles when cholesterol concentrations of 30-50%; this means that the amount of the surfactant i.e. B56 would be at least 10% of the lipid vesicle, wherein the water/B56/cholesterol components in the lipid vesicle are in proportions of 2:0.5:5, respectively (column 8, lines 3-59; see table 1). To the extent that instant claim 6 recites the limitation *"monoenoic acyl groups constituting the diglyceride ... is about 10 to 84.5% by weight,"* this limitation overlaps with the teaching of Wallach regarding long-chain surfactants having at least one lipophilic acyl (i.e. polyoxyethylene acylated eicosamonoenoyl ether) or alkyl group attached to a hydrophilic head group. Applying the same analysis to the polyoxyethylene acylated eicosadienoyl group as taught by Wallach, the limitation of *"wherein a content of omega-3 unsaturated acyl groups having at least 20 carbon atoms ... constituting the diglyceride is [sic] about 15 to 89.5%"* would necessarily overlap with the reference teaching when the proportion of water/B56/cholesterol components in the lipid vesicle are in proportions of 5.6:1.4:3, respectively. Furthermore, the lower range of *"about 15%"* of the acyl groups recited in claim 6 is reasonably interpreted to include amounts of 10% percent of either C20 carbon omega-3 unsaturated acyl groups and/or monoenoic acyl groups. Wallach teaches that if any hydrophilic materials are to be

incorporated within the lipid vesicles, they should be added to the aqueous phase before combining with the lipophilic phase (column 4, last line to page column 5, line 3). Wallach teaches that the vesicles may also include targeting molecules, either hydrophilic or amphiphilic, which can be used to direct the vesicles to particular targets in order to allow release of the material encapsulated in the vesicle at a specified biological location (column 5, line 29 to column 6, line 59). Wallach teaches that one of the advantages of the referenced materials and processes is that the surfactants used have relatively low melting points so materials which are temperature sensitive can be encapsulated without damage (column 6, lines 53-59).

The above discussions of Stout et al., Brown et al. (5,288,619), Seiden et al. (US Patent 4,680,184), Ainger et al. (US Patent 4,214,012), Maurrizio Ciani, and Young et al. (US Patent 5,085,884), are incorporated by reference.

Based on the teaching of lipid vesicles for incorporating hydrophilic materials by Wallach, someone of skill in the art at the time the instant invention was made would have been motivated to combine the teachings of Wallach, in view of Stout et al., in view of Brown et al. (5,288,619), in view of Martin et al. (US Patent 3,168,405), in view of Seiden et al. (US Patent 4,680,184), in view of Ainger et al. (US Patent 4,214,012), in view of Maurrizio Ciani, and in view of Young et al. (US Patent 5,085,884).

Thus, it would have been obvious to someone of skill in the art at the time the instant invention was made to create the instant invention with a reasonable expectation of success in view of Wallach, in view of Stout et al., in view of Brown et al. (5,288,619), in view of Seiden et al. (US Patent 4,680,184), in view of Ainger et al. (US Patent

4,214,012), in view of Maurrizio Ciani, and in view of Young et al. (US Patent 5,085,884).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 9 a.m. to 5:30 p.m. Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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